UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ALPHAVAX, INC., Plaintiff,	)	
v.	)	CIVIL ACTION NO. 09-11176-WGY
NOVARTIS VACCINES AND DIAGNOSTICS, INC., Defendant.	)	

ORDER

YOUNG, D.J. June 29, 2010

I. INTRODUCTION

This action is an appeal under 35 U.S.C. § 146 of a final decision and order (the "Decision") of the Board of Patent Appeals and Interferences ("Board") of the U.S. Patent and Trademark Office ("PTO") in Interference Number 105,456, which established the priority of U.S. Patent 6,015,694 (the "'694 Patent") over patent application number 10/683,781 (the "'781 Application"). AlphaVax, Inc. ("Avax") asks this Court to review the Board's decision on priority. It also asks this Court to rule on questions as to the patentability of the '694 Patent based on anticipation and lack of enablement, which were presented to the Board but never decided. Avax moves for summary judgment on the issues of anticipation and lack of enablement.

Novartis Vaccines and Diagnostics, Inc. ("Novartis") moves for summary judgment affirming the Board's priority determination.

A. Background

1. The Invention

Novartis is the owner by assignment of the '694 Patent. Avax is the exclusive licensee of the '781 Application. The Board determined that claim 9 of the '694 Patent and claim 38 of the '781 Application are directed to the same subject matter. Decision at 2-3.[1]

The invention at issue is a vaccination method against alphavirus caused disease. In claim 9, the '694 Patent claims a method for generating an immune reaction in a host patient or an animal against an antigen.[2] The '694 Patent col.214 l.28-29. Many antigens are not readily susceptible to being directly injected into the host. Thus, claims 9-11 encompass a process

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[1] Novartis manually filed interference record ("I.R."). The Decision was filed as a part of the interference record. I.R. 005389-005414.

[2] Claim 9 reads:

> A method of stimulating in an animal an immune response to an antigen, comprising infecting susceptible animal target cells with recombinant alphavirus particles which direct the expression of at least one antigen or modified form thereof in target cells infected with the alphavirus, wherein said antigen or modified form thereof stimulates an immune response within an animal, and wherein said recombinant alphavirus particles are free from recombinant alphavirus particles that can initiate a productive infection that yields infective alphavirus particles.

The '694 Patent col.214 l.28-37.

wherein the nucleic acid (RNA) that expresses the antigen is introduced to the cells of a host by means of an alphavirus. The infected cells of the host express the antigen, which when released into the host's body, generates an immune response. Id. col.214 l.29-30.

The alphavirus used to infect the host cells contains two important alterations. First, the virus has been altered to include RNA that expresses the antigen, referred to as a heterologous protein. Id. col.214 l.31-35. This was a relatively well-known technology by 1995. Kelber Decl. Ex. 2018 ¶ 8. When the virus infects the cell, the virus RNA takes over the cellular apparatus, and makes many copies of itself, including the antigen in question. Id. The host's immune system hopefully then generates an immune response to the expressed heterologous protein (sometimes called a transgene).

The second alteration, according to the '694 Patent, is that the alphavirus is free of replication competent virus ("RCV-free"). The '694 Patent col.214 l.35-37. This alteration of the alphavirus is the one that poses a significant barrier to the technology. Alphaviruses are themselves capable of infecting animals and humans, even resulting in death. Kelber Decl. Ex. 2018 ¶ 8. Before the alphavirus can be used, it is necessary to alter the alphavirus to render it incapable of generating more virus particles that can infect the host. This is not easy as the virus needs all of its RNA to make the many copies required for the technology. The answer is to separate the RNA into

different pieces, or "helper" RNA, in hopes of avoiding generation of a complete copy of the RNA and a replication competent virus. Id. ¶¶ 9-11. This proves difficult to do because the enzymes the virus uses "switch" from one piece of RNA to another, synthesizing the entire RNA of the virus, and thus RCV. Id. ¶¶ 9-18.

2. Proceedings before the Board

This dispute has had a long history in the PTO. Decision at 3-8. The '694 Patent was issued on January 18, 2000. Kelber Decl. Ex. 20111. After several unsuccessful attempts, Avax initiated an interference proceeding with its '781 Application. Decision at 7. Avax was declared the "junior party" in the interference because its earliest application filing date was after Novartis' earliest filing date. I.R. 000001. As the junior party, Avax was required to provide an explanation in its request for a declaration of interference detailing how it would prevail on priority. 37 C.F.R. § 41.202(a)(4). The explanation in Avax's request was the following:

> Applicants also note that 37 CFR 41.202, like 37 CFR 1.608 before it, requires a statement of how Applicants will prevail on priority. The corroborated Declarations of the inventors (Davis and Johnston, Ludwig, Parker, Pushko and Smith) corroborated by Caley (working with Davis and Smith), Lind (working with Parker, Pushko and Ludwig) and Lofts (working with Smith, Parker, Pushko and Ludwig), demonstrate conception and reduction to practice of the invention at issue in advance of the patentee. . . . In prosecution, the earliest possible date for the subject matter of Claim 9 of the '694 patent was identified by Examiner Mosher as November 30, 1994. Applicants' conception and actual reduction to practice, first via in vitro studies, then in vivo studies involving laboratory mice, were completed long prior to

> this date. Applicants' conception, and diligence toward an actual reduction to practice, begins prior to the earliest filing date of the parentage of the '694 patent, September 15, 1993. Accordingly, prima facie applicants are entitled to priority and judgment vis-a-vis the '694 patent, and declaration of an interference therewith is respectfully requested.

Decision at 6-7 (citing the '781 Application, Request for Reconsideration, at 4-5 (Nov. 16, 2005)).

The Board ruled this Request insufficient and ordered Avax to show cause why judgment ought not be entered against it. I.R. 000093-96. Avax's Order to Show Cause briefing included its Response to the Order to Show Cause, Substantive Motion 1 (challenging Novartis' priority date based on an enablement challenge), and Substantive Motion 2 (a contingent motion to substitute a count). I.R. 000146-59, 000160-76, 000204-14. In addition, Avax filed two other substantive motions attacking the patentability of the '694 Patent on the basis of anticipation and lack of enablement. I.R. 000358-72, 000406-21. The parties fully briefed and argued before the Board both the priority and the patentability issues. Pl.'s Statement of Facts ¶¶ 8-10 [Doc. No. 22]; Def.'s Resp. to Pl.'s Statement of Facts ¶¶ 8-10 [Doc. No. 27]. Ultimately, the Board ruled that Avax had failed to carry its burden of proof in response to the Order to Show Cause as to priority. Decision at 2. The Board also denied Avax's Substantive Motions 1 and 2. Id. The Board took no action on Avax's patentability motions. Id.

B. Federal Jurisdiction

This Court has jurisdiction to review actions of the PTO Board. 35 U.S.C. § 146. The parties agree that the Court has jurisdiction to review the Board's decision as to priority. They dispute, however, whether the Court has jurisdiction to decide questions of anticipation and enablement, which were raised before the Board but never resolved by it.

"The Board of Patent Appeals and Interferences shall determine questions of priority of the inventions and may determine questions of patentability." 35 U.S.C. § 135(a). The statutory language is clear: it mandates but does not require the Board to adjudicate issues of patentability.

After ruling that Avax failed to establish a prima facie case on priority, the Board did not make any decision on Avax's motions regarding anticipation and enablement as such findings and rulings were unnecessary. Novartis argues that because the Board took no action on the patentability issues, this Court has no jurisdiction to adjudicate them. Avax suggests that the Board erred in failing to decide the patentability issues because they were properly raised and developed before the Board. The question before the Court is whether the Board was required to rule on the patentability of the '694 Patent even though Avax had failed to establish a prima facie case of priority.

Avax argues that the Board should have decided its motions concerning patentability because doing so is consistent with the legislative intent to provide complete resolution of the rights between parties and rights of concern to the public. Perkins v. Kwon, 886 F.2d 325, 328-29 (Fed. Cir. 1989) (describing legislative purpose as determination of both priority and patentability when fully presented in interference proceedings because it would settle not only the rights between parties but also the rights of concern to the public). Avax also suggests that despite having lost the right to its patent as a result of an adverse decision on priority, Avax still has an interest in seeing that Novartis is likewise not entitled to the subject matter of the interference, albeit on patentability, not priority, grounds. See Wu v. Wang, 129 F.3d 1237, 1241 (Fed. Cir. 1997).

Avax argues that "the Federal Circuit has repeatedly held that the District Courts should decide [issues of patentability], whenever they are properly and fully raised before the Board." Pl.'s Reply at 4 [Doc. No. 37]. The cases cited by Avax, however, only establish that the Board is **authorized** to decide issues of patentability properly raised before it, not that the Board is **compelled** to decide them.

Avax quotes Perkins as support, which stated that "issues of patentability and priority that have been fully developed before

the Board should be resolved by the Board." 886 F.2d at 328. This quote is taken out of context. In Perkins, the Board held that neither party to an interference was entitled to a patent since the Board determined that Perkins was not the first to invent and Kwon lost on the patentability of his patent. Id. at 325. The Federal Circuit was presented with the question of whether the Board had authority to address both priority and patentability issues; the court was never presented with the question of whether the Board was compelled to address them. Similarly in Wu, the Federal Circuit only upheld the Board's decision to rule on both priority and patentability issues presented before it, stating that the Board has the right to do so if these issues are fully and fairly raised before it. 129 F.3d at 1239.

Avax also cites Koninklijke Philips Elec. N.V. v. Cardiac Science Operating Co., stating that "the Board should decide issues relating to . . . patentability that are fairly raised and fully developed during the interference, despite the permissive language of § 135(a) with respect to patentability issues." 590 F.3d 1326, 1336 (Fed. Cir. 2010) (quoting In re Gartside, 203 F.3d 1305, 1317 (Fed. Cir. 2000)) (emphasis in original). Gartside, however, only quotes this language from Perkins, discussed above without elaboration on the issue. Gartside, 203 F.3d at 1317. Neither Koninklijke, nor Gartside provided

independent analysis of the question or faced the same situation that is now before this Court. See Gartside, 203 F.3d at 1317 (determining that a party's withdrawal from an interference did not divest the Board of jurisdiction to decide questions of patentability that were fairly raised and fully developed during the proceeding); Koninklijke, 590 F.3d at 1336 (reversing the district court ruling, which upheld the Board's decision on the patentability issue because it failed to apply the correct standard).

Thus, none of the cases cited by Avax suggest that the Board is under an obligation to review all the issues presented before it. This conclusion is further supported by the the Federal Circuit's analysis in Berman v. Housey, 291 F.3d 1345, 1353 (Fed. Cir. 2002) (stating that no case cited by plaintiff, including Wu, Perkins, and Gartside, concerned whether the Board is compelled to decide questions of patentability). Avax argues that Berman is not applicable because the court there upheld the Board's refusal to rule on the patentability question on the basis that the party challenging patentability was barred from contesting interference under 35 U.S.C. § 135(b) and the Board, therefore, had no jurisdiction to determine either priority or patentability.[3] Though the court in Berman decided not to base

[3] It should be noted that Novartis focuses its jurisdiction argument not on the discretionary nature of the Board's authority to review questions of patentability, but on the notion that the

its decision on the notion that the Board's determination of patentability is discretionary, its analysis of the question is persuasive.

Avax also makes an argument that 35 U.S.C. § 6(b), which provides in relevant part that the Board "shall determine priority and patentability of invention," requires the Board to do so. The same argument was addressed in Berman, where the Federal Circuit stated that "the legislative history of §§ 6 and 135 makes clear that those provisions address only what issues the Board is empowered to consider, and thus does not establish any affirmative obligations that it must perform." Berman, 291 F.3d at 1353-54 (citing 130 Cong. Rec. H10525, H10528 (1984), reprinted in 1984 U.S.C.C.A.N. 5827, 5836).

Because the Board was not obligated to rule on the patentability questions presented by Avax, it did not err in choosing not to do so. Thus, this Court declines to consider the issues of anticipation and lack of enablement. Avax is not totally foreclosed from arguing that the '694 Patent is invalid, but it must do so outside this section 146 appeal. In such a

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failure by Avax to establish a prima facie case, like the 35 U.S.C. § 135(b) error in Berman, made interference non-existent. This argument is not persuasive, however, because the Board's decision considered the merits of the case and determined who was first to invent the subject matter. In Berman, the Board determined only that Berman's claim was procedurally barred because it was made more than one year after the issuance of the disputed patents. 291 F.3d at 1351.

case, however, Avax will be subject to a higher burden of proof – clear and convincing evidence – because, unlike in an interference proceeding, the '694 Patent will be entitled to the presumption of validity. Cf. Environ Prods., Inc. v. Furon Co., 215 F.3d 1261, 1265 (Fed. Cir. 2000) (holding that where the patent in question was copending with the application involved in the interference, the burden of the proof on a party challenging validity is merely a preponderance of the evidence).

II. ANALYSIS

A. Standard of Review and Admission of Further Evidence

The Federal Circuit has "often described the district court proceeding as a hybrid of an appeal and a trial de novo." Winner Int'l Royalty Corp. v. Wang, 202 F.3d 1340, 1345 (Fed. Cir. 2000) (internal quotation marks omitted). A district court reviews the Board's conclusions of law de novo. See Gartside, 203 F.3d at 1315. The situation with respect to findings of fact is more complicated, however, because section 146 calls for review "without prejudice to the right of parties to take further testimony." 35 U.S.C. § 146. If the district court does not receive any new evidence or live testimony, it applies the substantial evidence test. See Mazzari v. Rogan, 323 F.3d 1000, 1005 (Fed. Cir. 2003). If the court receives new evidence or live testimony, however, the court must make factual findings de novo at least with regard to the issues on which live testimony is taken. See Winner, 202 F.3d at 1347-48 & n.4.

Avax asks this Court to admit the live testimony of the inventors and corroborators on the issue of priority and to hear the live testimony of expert witnesses in connection with its reviewed motions. Novartis argues that additional testimony ought not be allowed.

Though the equitable character of the district court's review under section 146 allows the court to admit new testimony when equity so requires, Conservolite v. Widmayer, 21 F.3d 1098, 1102 (Fed. Cir. 1994), section 146 does not address the issue of when it is appropriate to do so. It is clear that the interference hearing was not intended as a rehearsal before the case will be reconsidered in the district court. See id. at 1102. "The viability of the administrative process presupposes that pertinent and available testimony will be presented before the appropriate administrative body." Kirschke v. Lamar, 426 F.2d 870, 874 (8th Cir. 1970). On the other hand, live testimony may not be presented in the interference proceedings before the PTO Board. Winner, 202 F.3d at 1347 (citing 37 C.F.R. §§ 1.653(a), 1.677(a)). In Cell Genesys, Inc. v. Applied Research Sys. ARS Holding, N.V., 499 F. Supp. 2d 59, 74-76 (D. Mass. 2007) (Wolf, C.J.), the court declined to admit new testimony and after detailed analysis, stated that the introduction of new testimony is only warranted either to enhance the accuracy of judgments concerning credibility or to present evidence that was not available despite due diligence at the time of the Board's proceedings.

In a very similar case, Invitrogen Corp. v. President & Fellows of Harvard Coll., 578 F. Supp. 2d 248 (D. Mass. 2008) (Gorton, J.) the court, decided not to admit live testimony citing Cell Genesys. 578 F. Supp. 2d at 255. There, after an interference proceeding, the Board held that Invintrogen failed to establish a prima facie case on priority in part because the Board could not understand the unexplained lab notebook entries of the inventors. Id. at 256. On review, Invitrogen moved to admit live testimony from inventors to explain those pages and bolster the inventors' declarations. The court stated that, though it might be helpful to hear live explanations now, "Invitrogen had [the] opportunity to reference such information for the Board in its principal brief but failed to do so. It will not now get a 'do over' in this Court." Id. Moreover, the court explained that the Board did not make a determination of credibility, but rather established that the evidence provided was insufficient as matter of law. Therefore, introduction of live evidence was not appropriate. Id.

So here. In the present case, the Board held that Avax provided insufficient evidence to support a prima facie case on priority. Decision at 11. The Board's decision was based on the absence from the corroborators' declarations of "any facts related to work on the subject matter of the invention" as well as on the Board's inability to find support for Avax's priority

story in the hundreds of pages of unexplained exhibits.[4] Id. at 12. The Board's decision was not based on an evaluation of credibility.

Avax argues, however, that the Board's decision was in fact based "nearly entirely on the issue of credibility - is the story of the Avax inventors believable." Pl.'s Opp'n to Def.'s Mot. at 19. Determination of priority is always based on the question of whether the Board accepts a potential inventor's story. This does not mean, however, that the Board's decision always involves an evaluation of credibility. As in Invitrogen, or in the present case, the Board may decide that the presented evidence is merely insufficient, even if given full credit.

Therefore, though it may be helpful to hear live testimony that can provide guidance through the voluminous record, Avax ought not be allowed a chance to "do over" what it has chosen not to do before the Board. Because it is inappropriate to admit new evidence, the Court will review the decision of the Board on the existing record using the substantial evidence test.

B. Decision of the Board

The Board decided that Avax failed to show good cause why the decision on priority ought not be entered against it because Avax failed to show that its request for an interference provided an adequate explanation showing how it would prevail on priority

[4] See section II.B.1 for more detailed discussion of all the evidence presented before the Board.

as required by 37 C.F.R. § 41.202. The Board further denied Avax's motion attacking giving Novartis the benefit of the '694 Patent's parent application ("the '796 Application") filing date. The Board also denied Avax's motion to substitute a new count to insert the additional limitation that alphavirus particles were RCV-free "as determined by passage on permissive cells in culture," which was based on the notion that claim 9 of the '694 Patent would otherwise be indefinite or would encompass multiple patentably distinct inventions.

1. Decision on the Order to Show Cause

Avax argues that in ruling against it on the order to show cause, the Board did not give sufficient weight to the declarations of corroborating witnesses and that the Board failed to evaluate the full record that was before it.

A party demonstrates priority either by proving that it was the first to reduce an invention to practice or by proving that it was the first to conceive the invention and exercised reasonable diligence in later reducing that invention to practice. Price v. Symsek, 988 F.2d 1187, 1190 (Fed. Cir. 1993). Avax submitted three types of evidence to establish priority: declarations of the inventors, declarations of non-inventors ("corroborators"), and exhibits including inventor's lab notebooks. Under 37 C.F.R. § 41.202(a)(4), an applicant suggesting interference must "[e]xplain in detail why the

applicant will prevail on priority." In its request for interference, Avax included one paragraph purporting to explain how it will prevail on priority:

> The corroborated Declarations of the inventors (Davis and Johnston, Ludwig, Parker, Pushko and Smith) corroborated by Caley (working with Davis and Smith), Lind (working with Parker, Pushko and Ludwig) and Lofts (working with Smith, Parker, Pushko and Ludwig), demonstrate conception and reduction to practice of the invention at issue in advance of the patentee. . . . In prosecution, the earliest possible date for the subject matter of Claim 9 of the '694 patent was identified by Examiner Mosher as November 30, 1994. Applicants' conception and actual reduction to practice, first via in vitro studies, then in vivo studies involving laboratory mice, were completed long prior to this date. Applicants' conception, and diligence toward an actual reduction to practice, begins prior to the earliest filing date of the parentage of the '694 patent, September 15, 1993. Accordingly, prima facie, applicants are entitled to priority and judgment vis-à-vis the '694 patent, and declaration of an interference therewith is respectfully requested.

Decision at 6-7 (citing the '781 Application, Request for Reconsideration, at 4-5 (Nov. 16, 2005)). Reference was made only to the declarations of Caley, Lind, and Lofts as corroborating evidence; no further guidance was provided for the Board such as references to any corroborating documents.

A party seeking to prove conception via testimony of a putative inventor must proffer evidence corroborating that testimony. Singh v. Brake, 222 F.3d 1362, 1367 (Fed. Cir. 2000). It is undisputed that the Board correctly held that declarations of the inventors are insufficient as matter of law to establish priority. Avax argues, however, that the Board did not give sufficient weight to the declarations of corroborating witnesses.

Analyzing the corroborators' declarations, the Board noted that all of them only testified that they "'saw activities that are entirely consistent with' assertions" made in the inventors' declarations. Decision at 12. The Board concluded that these declarations did not provide sufficient corroboration because they were "devoid of any facts related to work on the subject matter of the invention." Id. at 13. Avax claims that the declarations are sufficient under circumstances where elaborate measures were taken to ensure safety and confinement of viruses and "an over the shoulder" observation was not possible. Pl.'s Opp'n at 5 n.5, 7. The Board expressly noted that it did not apply "an over the shoulder" standard but a "rule of reason" analysis to determine sufficiency of corroboration. Decision at 13; see Singh, 222 F.3d at 1367. The Board was reasonable in determining that the declarations of the corroborators were insufficient to support the inventors' position due to generality and vagueness.

Avax further argues that the Board erred when it did not take into consideration the inventors' lab notebooks. In its decision the Board stated that it attempted to search the voluminous unexplained documentary record for evidence to support Avax's priority story, but was unable to do so as it was not directed to specific pages. The Board correctly noted that the lab notebooks were poorly explained and in many places barely

legible. Decision at 12. More importantly, unwitnessed documents prepared by the inventors, even if correctly explained, are insufficient to corroborate the fact of actual reduction to practice or diligence toward it. Hahn v. Wong, 892 F.2d 1028, 1032 (Fed. Cir. 1989) ("The inventor . . . must provide independent corroborating evidence in addition to his own statements and documents."). Singh, cited by Avax, is not to the contrary. It states that a "notebook page may well show that the inventor conceived what he wrote on the page, whereas it may not show that the experiments were actually performed, as required for a reduction to practice." Singh, 222 F.3d at 1370. To establish a prima facie case on priority, Avax needed to provide evidence on both conception and actual reduction into practice (or diligence towards it). Unwitnessed inventors' notebooks are insufficient as matter of law.

Finally, Avax argues that the Board erred when it failed to give enough weight to the document titled "ILIR Proposal" referenced in Smith's declaration, which represented a document signed by a non-inventor.[5] The Board explained that the document was not directed to its attention in the showing required by section 37 C.F.R. § 41.202(a)(4). Even if given full credit, this document only refers to the conception of the invention and

[5] This document consists of a one sentence memorandum signed and dated by Jeffery D. Chulay, and an attached ILIR Proposal, which is not signed or dated, but connected to the memorandum only by the inventor's testimony. Kelber Decl. Ex. G.

thus is insufficient to corroborate a full prima facie case for priority.

The Board's decision on the order to show cause was supported by substantial evidence.

2. Decision on Motion Attacking Benefit

Avax further alleges that the Board erred in denying its motion attacking granting Novartis the benefit of the '796 Application filing date. Avax argued before the Board that the '796 Application lacked enabling disclosure because (1) the stock of modified alphavirus produced according to Dubensky's disclosure would not be RCV-free and (2) no assay for determining whether the particles were RCV-free was disclosed.

A patent's specification must contain sufficient disclosure to enable a person skilled in the art to practice the invention without undue experimentation. Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1334 (Fed. Cir. 2003). The invention at bar requires the use of alphavirus that are RCV-free. Thus, if the specification fails to disclose a working technique to produce such RCV-free alphavirus, the patent will be invalid for lack of enablement. Furthermore Avax, as a party who brought the motion before the Board, had the burden of proof to show lack of enablement. 37 C.F.R. § 41.121(b).

Concerning the first argument, the Board determined that Avax primarily relied on a paper subsequently published by the

'694 Patent inventors that allegedly indicates that the alphavirus generated according to Example 7B4 of the '796 Application were not RCV-free. Decision at 20. After reviewing the article, the Board concluded that Avax failed to establish that the article described the same technique that was taught in the '796 Application (or one that was not materially different). Id. Without Avax's guidance to the contrary (and there is none), this Court gives deference to the Board's evaluation of this technical article as not necessarily describing the same method that was mentioned in the Example 7B4. Decision at 20.

The Board in its decision did not discuss the expert testimony on this issue. Avax's expert testified that the '796 Application contains Example 7B4, which proposes a method for production of the RVC-free alphavirus. Kelber Decl. Ex. 2018 ¶ 20. Avax's expert noted, however, that without supporting data it was unclear whether that method would work. Id. This testimony does not state that the method does not work. It is thus insufficient to establish lack of enablement.

Concerning the second argument, Avax's expert pointed out that the '796 Application did not disclose any assay for determining whether the particles were RCV-free. Id. ¶¶ 19-22. The Board acknowledged this, but concluded that Avax failed to establish lack of enablement because it never made a showing that suitable assays were not known to persons skilled in the art.

Decision at 20. This conclusion utilized the correct legal rule – that specifications need not disclose something that is known to a person skilled in the art. See S3 Inc. v. NVIDIA Corp., 259 F.3d 1364, 1371 (Fed. Cir. 2001). It was further bolstered by the fact that Avax's expert declaration does not state that preparation of a suitable assay was not known to a person skilled in the art. Kelber Decl. Ex. 2041. Moreover, that declaration even gives an example of a well-qualified assay that can be used for the detection of the alphavirus replication. Id. ¶ 11. This Court concludes that the Board's decision on the motion attacking benefit as to application date was supported by substantial evidence.

3. Decision on Motion to Substitute New Count

The Board rejected Avax's motion to redefine the subject matter of the invention (by substituting a new count) by inserting the additional limitation that alphavirus particles are RCV-free "as determined by passage on permissive cells in culture." Avax argued that absent such limitation, claim 9 of the '694 Patent is indefinite or encompasses multiple patentably distinct inventions. Avax does not here present any argument why the Board's decision on this motion was incorrect.

Concerning the indefiniteness issue, the Board noted that the boundary of the invention plainly is described as alphavirus particles "free of recombinant alphavirus particles that can

initiate a productive infection that yields infective alphavirus particles." The '694 Patent col.214 l.34-36. This description is amenable to construction and is not insolubly ambiguous. See Exxon Res. & Eng'g Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001). Thus, the determination of the Board is reasonable.

Concerning the second argument, the Board stated that:

> [a]ssuming Claim 9 is "generic" to numerous protocols and utilities, [Avax's] motion does not explain why these protocols and utilities are separately patentable over each other, i.e., that protocols would not be anticipated or be obvious to a person skilled in the art over each other assuming each of the protocols, in turn, is prior art vis-a-vis the others.

Decision at 25. Absent argument to the contrary, the Court holds that the Board's decision was reasonable.

III. CONCLUSION

The Court DENIES Avax's motion for summary judgment and GRANTS Novartis's motion for summary judgment. The decision of the Board is upheld and judgment shall enter so declaring.

SO ORDERED.

/s/ William G. Young

WILLIAM G. YOUNG
DISTRICT JUDGE